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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/215,095	12/18/1998	NATHANIEL T. BECKER	GC507-2	7801

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/23/2002

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/215,095

Applicant(s)
Becker et al

Examiner
Michael Borin

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1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-98 is/are pending in the application.
- 4a) Of the above, claim(s) 70, 71, and 77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-69, 72-76, and 78-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 31
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Continued examination under 37 CFR 1.114 after final rejection

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/01 has been entered.

Status of claims

2. Claims 66,78,83,84 are amended. Claims 89-98 are added. Claims 66-69, 72-76, 78-98 are under examination. Claims 70, 71, 77 remain withdrawn from consideration as drawn to non-elected species.

3. Applicants arguments are focused on the presence of a "single" seed in the granules as claimed. Claims 66,83 are amended to replace language "a seed particle" with "an individual seed particle". Applicant's position that the claims are thus drawn to granules having only one seed particle, and that such granules are not anticipated by the prior art. Although Examiner acknowledges that the prior art used in the rejections does not teach granules having only one seed particle, Examiner

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disagrees that the claims are limited to such granules. First, the claims have open "comprising" language, which allows for the presence of other components, e.g. other seeds, in the granule. Second, the claims do not recite "single" seed, rather they recite an "individual" seed. The latter can be interpreted not as a single seed present in a granule, but also as a separate unclustered seed, as opposed to agglomerate of more than one individual seed. Third, there is nothing in the specification showing that there can not be more than one seed per granule. See, e.g., Example 1, p. 11. Consequently, the rejections of record are maintained for the reasons set forth in Office action mailed 3/5/01 (paper #17).

4. Claims 66-69, 72,74,78,79,82-86, 91,92,93,95-97 remain rejected under 35 U.S.C. 102(b) as anticipated by Kiesser et al. (US Patent 5,739,091)

Kiesser

Kiesser et al. teach enzyme granules. The granules are prepared by spraying of enzyme concentrate over pre-mix of pulverant particles (interpreted as "seeds" of the instant claim language). See col. 4, lines 21-24. The granules comprise enzyme or enzyme mixture and excipients that augment storage stability of enzymes, such as sugars (e.g., glucose). Further, the granules comprise inorganic salts (read on "barrier layer" of the instant invention, see specification, p. 8, bottom). Further, the granules comprise fillers, such as cellulose. See column 1, lines 31-67, column 2, line

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66 to col. 3, line 4. The granules may further comprise binders, such as polyethyleneglycol. See col. 2, lines 16-24. The granules may be covered with a protective coating (col.4, lines 5-11). The coating can contain sugars (col. 4, lines 8-10) or polyethyleneglycol (col.4, line 46). Note, that as the instant claims have open "comprising" language, they read on granules having more than one individual seed in the granule

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed by the teaching of the reference cited above.

5. Claims 75,76,80,81,87,88, 92-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiesser et al. (US Patent 5,739,091). The reference is used as applied to claims 66-69, 72,74,78,79,82-98 in the preceding paragraph. The reference does not teach all particular enzymes, all particular cellulose-derived fillers, and particular barrier layer materials as instantly claimed. Selection of particular enzymes would be *prima facie* obvious as the reference teaches enzyme granules in general and is not limited to any particular enzyme. As for the selection of cellulose derivatives as fillers and selection of barrier layer materials, such excipients are well know to be used for this purpose, and their selection would be obvious for an artisan to be achieved in a way of ordinary optimization.

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6. Claims 66-69, 72-76, 78-88 remain rejected under 35 U.S.C.103(a) as obvious over Martussen (EP 304332).

Claims 1-3, 5,6-11,23-25,27-33, 57-65 are rejected under 35 U.S.C.103(a) as obvious over Martussen (EP 304332).

Martussen

Martussen teaches enzyme granules comprising a core (which is equivalent to "seed" as claimed) and a coating. The enzyme can be either included in the core (which is the only embodiment discussed by applicants) or located in the coating surrounding the core. p 2, lines 13-19. In the latter case, the core is any coherent non crumbling material, such as sodium chloride. p 2, lines 29-31. The coating comprises cellulose or artificial binders, such as polyvinyl pyrrolidone, cellulose derivatives, etc., and a granulating agent, such as polyglycols. See abstract, pages 2-3. Also, other additives, such as coloring agent coating can be added. p. 3, lines 48,49. The reference does not explicitly teaches the presence of sugars in the granule. However, addition of such ingredients would be *prima facie* obvious when the enzyme granulates are to be used as nutrient additives, because the reference teaches that if the granules are to be used as nutrient additives, the enzyme (which can be either inside the core or in the surrounding coating) can be mixed with starch, sugars or proteins. See p. 2, lines 32-34.

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Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 89,90 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification as filed does not describe the ratios as now claimed.

8. Claims 92,96 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification as filed does not describe any barrier layer materials other than inorganic or organic salts.

Prior art made of record

9. The prior art which has been made of record previously and not relied upon is considered pertinent to applicant's disclosure:

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US 4106991 teaches use of cellulose (polysaccharide) as structuring agent in preparation of enzyme granules.

US patents 4689297, 5324649, and WO 97/12958, WO 9932595 describe use of various core particles as seeds in forming enzyme granules.

9. This is an RCE of Application No. 09/215095. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

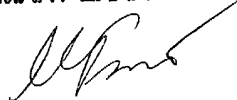
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER



April 4, 2002

mlb